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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/17/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/823,840

Applicant(s)

TERASHIMA ET AL.

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 3-30-2000. It is noted, however, that applicant has not filed a certified copy of the application as required by 35 U.S.C. 119(b).

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 27. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The disclosure is objected to because of the following informalities: On page 2, lines 12 and 13, it is unclear what is meant by the phrase "the pH value of the blood *teaches* an acid-base balance in the blood" (emphasis added). This would appear to be an idiomatic error remaining as a result of the translation of the foreign application.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In claims 1, 9, and 15, the phrase "which are electrically separated" is indefinite because it is unclear whether the applicant is specifying that the Ag is separated from the AgCl or if each of the Ag/AgCl portions are separated from each other. For the purpose of applying prior art, the examiner has interpreted it as the latter, but clarification is requested.

7. In claim 1, the discussion of "a pair of electrode units" in the limitations of the claim concerning the hydrogen ion selective electrode (ISE) is confusing because the exact term was also utilized above with respect to the calcium ISE. The examiner recommends unique terms be utilized for each pair of electrode units.

8. In claims 1, 9, and 15, there is no antecedent basis for the term "the composite electrode". Applicant has not defined what the composite electrode represents of the above specified structure. In addition, it is unclear if the second occurrence of the term "composite electrode" in each of the claims is meant to read on the first set forth composite electrode. For claim 1, it would appear the first occurrence of "the composite electrode" is drawn to one of the pair of calcium electrodes and one of the pair of hydrogen electrodes, while the second occurrence of "the composite electrode" is drawn to the other electrodes of each pair, but clarification is requested.

9. In claim 1, section (3), the use of the terms "one member" and "another member" is confusing. Applicant has repeatedly utilized the term "member" earlier in the claim rendering it

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unclear what these two terms are specifically referring to. It appears applicant is referring to the pair of distributing members, but the claim should utilize a specific term for each of these elements.

10. In claim 1, it is unclear what the terms "one electrode unit" and "another electrode unit" are referring to.

11. In claims 2, 3, 10, 11, applicant refers to a particular molecule containing a (1, 1, 1, 3-tetramethylbutyl) unit. The examiner does not believe such a molecule exists because three methyl groups cannot be attached to the 1-carbon of this butyl unit. There are only two sites available on the 1-carbon for methylation (the other two bonding sites are taken by the connection to the phenyl group and the 2-carbon). The specification also specifies the use of the 1, 1, 1, 3 material. For the purpose of applying prior art, the examiner is interpreting the molecule in question as being drawn to a (1, 1, 3, 3-tetramethylbutyl) unit (see for example the reference Terashima), but clarification is requested.

12. In claims 3 and 11, the limitations drawn to the calcium...phosphate are redundant. Claims 2 and 10 already specified the inclusion of this molecule.

13. In claim 8, it is unclear what "respectively" is referring to.

14. In claim 8, the use of the term "means" at the end of the claim should be replaced with --is--.

15. In claim 16, the limitations drawn to dodecylamine and trimellitate are redundant with limitations already set forth in the preceding claim.

16. The preamble of claim 18 is confusing. Claim 15 is not a "composite ion selective electrode".

*Claim Rejections - 35 USC § 103*

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al (USP 4,437,970).

20. With respect to the claims as best understood, Kitajima teaches an ISE for materials such as calcium that comprises an electro-insulating support 28 having a pair of electrode units 26 comprising a silver layer and a silver halide layer (col. 10, lines 19-36), an electrolyte layer (col. 10, lines 59-66), and a calcium ion selective layer (paragraph bridging col. 10 and 11 and col. 11, lines 47-59). Kitajima further teaches an electro-insulating member 35 having two openings 36 that are provided on the electrode. One opening is for the introduction of sample liquid while the other is for the introduction of reference liquid (col. 6, lines 52-57). Kitajima further teaches a

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bridge member 38 that is provided on the electro-insulating member to bridge the two openings of the insulating member to provide electrical connection between the sample liquid and the reference liquid (col. 5, line 53 through col. 6, line 2). Kitajima further teaches the use of membrane thicknesses that overlap the claimed thickness (col. 11, lines 8-10). Although Kitajima teaches a broader range and does not teach the specific claimed range for a calcium membrane, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Kitajima with membranes in the narrower range from 5-30 (or 5 to 20 or 10 to 18) microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. In particular, thinner membranes would provide lower resistances and faster response times thereby providing rapid and accurate analysis.

21. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima in view of Chan (USP 5,911,862).

22. Kitajima set forth all the limitations of the claims, but did not explicitly identify the claimed phenyl phosphate for the calcium ion selective membrane (however, see 112 rejection above concerning the claimed phenyl phosphate). Chan teaches that the said phenyl phosphate is a conventional ion selective material utilized in calcium selective membranes (col. 16, lines 27-29). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Chan for the sensor of Kitajima because these materials have been shown to provide suitable ion selective materials for the analysis of calcium. In addition, the substitution of one equivalent ion selective material identified by the prior art for

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another requires only routine skill in the art. With respect to claim 11 (those limitations not covered above), Kitajima already set forth the use of vinyl chloride-vinyl acetate copolymers (col. 12, lines 60 and 61). Chan also sets forth the use of said copolymers as well as the use of dioctylphenyl phosphonate (col. 10, lines 44-59). With respect to claims 12 and 13, see the discussion above concerning membrane thicknesses.

23. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima and Chan as applied to claim 10 above, and further in view of Battaglia et al (USP 4,214,968).

24. The references set forth all the limitations of the claims, but Kitajima did not explicitly set forth the use of sodium chloride for the electrolyte. However, Kitajima suggested referring to USP 4,214,968 (i.e. Battaglia) for teaching of appropriate electrolytes (col. 10, lines 59-66). Battaglia teaches the use of sodium chloride as an electrolyte salt (col. 10, lines 22-37). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Battaglia for the sensor of Kitajima and Chan because Kitajima explicitly suggested doing so. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize sodium chloride as taught by Battaglia for the sensor of Kitajima and Chan because the material is conventional choice of salt in the art, and the interchanging of one known salt for another, when the results are not unexpected, requires only routine skill in the art.

*Allowable Subject Matter*

25. Claims 1-8 and 15-18 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.



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26. The following is a statement of reasons for the indication of allowable subject matter:

The prior art does not disclose nor render obvious an electrode comprising all the limitations of the claims 1 and 15 with particular attention to a hydrogen selective membrane of said electrode constructed with tri-n-dodecylamine and trisethylhexyl trimellitate.

### *Conclusion*

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ishizuka (H 745) teaches an electrode configuration like that shown in fig. 1 of the instant invention. Yun et al (USP 5,607,567) also teaches the use of the claimed components of the calcium ion selective membrane. Terashima (Fujifilm Research & Development 2001) appears to disclose the set forth invention, but would not appear to qualify as prior art under 35 U.S.C. 102(a). However, the examiner cannot determine the precise date of publication of the document and requests the applicant's assistance in determining the precise (or even approximate) date of publication. If the document was in fact published prior to 3-30-2001 (i.e. the US filing date of the instant invention), then the examiner requests the applicant provide a certified translation of Foreign priority document JP 2000-094333 to obviate a possible rejection under 35 U.S.C. 102 (a).

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on M-F 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden Sr. can be reached on 703-308-2920. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-5408 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in black ink, appearing to read 'Kaj K. Olsen', with a stylized flourish extending from the end.

Kaj K. Olsen  
Patent Examiner  
AU 1744  
July 12, 2002